CLAIMS:

1. A pharmaceutical dosage form comprising cedazuridine, or a pharmaceutically acceptable salt thereof, and azacitidine, or a pharmaceutically acceptable salt thereof, wherein at least a portion of the azacitidine is formulated for modified release.

2. The pharmaceutical dosage form of claim 1, wherein the cedazuridine is formulated for immediate release.

3. The pharmaceutical dosage form of claim 1 or 2, wherein the portion of the azacitidine that is formulated for modified release is formulated for enteric release.

4. The pharmaceutical dosage form of any one of the preceding claims, wherein the portion of azacitidine that is formulated for modified release is provided as minitablets comprising an enteric coat.

5. The pharmaceutical dosage form of claim 4, each azacitidine minitablet comprising:

about 20%-60% w/w of azacitidine, wherein the percentage by weight is relative to the total weight of the uncoated azacitidine minitablets; and

one or more pharmaceutically acceptable excipients.

6. The pharmaceutical dosage form of claim 5, wherein the one or more pharmaceutically acceptable excipients is selected from the group consisting of lactose monohydrate, microcrystalline cellulose, hydroxypropyl methylcellulose (HPMC), croscarmellose sodium, silicon dioxide, and magnesium stearate.

7. The pharmaceutical dosage form of any one of claims 4 to 6, wherein the enteric coat comprises polymethacrylate or copolymers thereof.

8. The pharmaceutical dosage form of any one of claims 4 to 7, wherein the enteric coat is sensitive to pH variations in the intestine.

9. The pharmaceutical dosage form of any one of claims 4 to 8, wherein each azacitidine minitablet further comprises a seal coat beneath the enteric coat.

10. The pharmaceutical dosage form of claim 9, wherein the seal coat comprises hydroxypropyl methylcellulose (HPMC).

11. The pharmaceutical dosage form of any one of the preceding claims, wherein the azacitidine is formulated for modified release and provided as minitablets comprising an enteric coat.

12. The pharmaceutical dosage form of any one of the preceding claims, wherein substantially all of the azacitidine is configured to be released outside the stomach.

13. The pharmaceutical dosage form of any one of the preceding claims, wherein the cedazuridine is uncoated and in the form of minitablets, a tablet, powder, blend, granules, or pellets.

14. The pharmaceutical dosage form of claim 13, wherein the uncoated minitablets, a tablet, powder, blend, granules, or pellets comprises about 10%-40% w/w of cedazuridine.

15. A pharmaceutical dosage form comprising cedazuridine, or a pharmaceutically acceptable salt thereof, and azacitidine, or a pharmaceutically acceptable salt thereof, wherein:

the cedazuridine is formulated for immediate release; and

the azacitidine is formulated as modified release minitablets comprising an enteric coat.

16. The pharmaceutical dosage form of claim 15, wherein each azacitidine minitablet comprises about 20%-50% w/w of azacitidine, wherein the percentage by weight is relative to the weight of an uncoated azacitidine minitablet.

17. The pharmaceutical dosage form of claim 15 or 16, wherein each of the azacitidine minitablets comprises an intragranular layer and an extragranular layer.

18. The pharmaceutical dosage form of claim 17, wherein the intragranular layer comprises about 20%-50% w/w of azacitidine, about 10%-60% w/w of lactose monohydrate, about 2%-60% w/w of microcrystalline cellulose, about 1%-10% w/w of croscarmellose sodium, about 0.5%-10% w/w of hydroxypropyl methylcellulose (HPMC), about 0.1%-3% w/w/ of silicon dioxide, and about 0.1%-3% w/w of magnesium stearate, wherein the percentage by weight is relative to the total weight of the uncoated azacitidine minitablets.

19. The pharmaceutical dosage form of claim 17 or 18, wherein the extragranular layer comprises about 1%-60% w/w of microcrystalline cellulose, about 1%-10% w/w of croscarmellose sodium, about 0.1%-3% w/w silicon dioxide, and about 0.1%-3% w/w of magnesium stearate, wherein the percentage by weight is relative to the total weight of the uncoated azacitidine minitablets.

20. The pharmaceutical dosage form of any one of claims 15 to 19, wherein the enteric coat comprises polymethacrylate or copolymers thereof.

21. The pharmaceutical dosage form of any one of claims 15 to 20, wherein the enteric coat is sensitive to pH variations in intestine.

22. The pharmaceutical dosage form of any one of claims 15 to 21, wherein each azacitidine minitablet further comprises a seal coat.

23. The pharmaceutical dosage form of claim 22, wherein the seal coat comprises hydroxypropylmethyl cellulose (HPMC).

24. The pharmaceutical dosage form of any one of claims 15 to 23, comprising azacitidine and cedazuridine in the weight ratio of from about 1:1 to about 1:3.

25. The pharmaceutical dosage form of any one of claims 15 to 24, comprising about 60 mg to 100 mg of azacitidine.

26. The pharmaceutical dosage form of any one of claims 15 to 25, wherein the cedazuridine is in the form of uncoated minitablets, tablet, powder, blend, granules, or pellets.

27. The pharmaceutical dosage form of claim 26, wherein the cedazuridine minitablets, tablet, powder, blend, granules, or pellets comprises about 10%-90% w/w of cedazuridine, wherein the percentage by weight is relative to the total weight of the cedazuridine uncoated minitablets, tablet, powder, blend, granules, or pellets.

28. The pharmaceutical dosage form of claim 26 or 27, wherein the cedazuridine minitablets, tablet, powder, blend, granules, or pellets further comprising about one or more selected from the group consisting of: lactose monohydrate, hydroxypropyl methylcellulose (HPMC), croscarmellose sodium, silicon dioxide, and magnesium stearate.

29. The pharmaceutical dosage form of any one of claims 15 to 28, comprising about 5 mg to 60 mg of cedazuridine.

30. A capsule comprising the pharmaceutical dosage form of any one of claims 1 to 29.

31. A capsule comprising:

one or more azacitidine minitablets formulated for modified release, comprising azacitidine or a pharmaceutically acceptable salt thereof, pharmaceutically acceptable excipients, and an enteric coat; and

immediate release cedazuridine in a form of uncoated powder or blends, comprising cedazuridine or a pharmaceutically acceptable salt thereof and pharmaceutically acceptable excipients.

32. Use of the pharmaceutical dosage form according to any one of claims 1 to 29 or the capsule according to claim 30 or 31, in the manufacture of a medicament for the treatment of cancer.

33. The use of claim 32, wherein the cancer is leukemia.

34. The use of claim 32, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), previously treated or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (AML) and chronic myeloid leukemia (CML), malignant peripheral nerve sheath tumors (MPNST), neurological cancer, breast cancer, hormone receptor positive tumor, head and neck cancer, primary central chondrosarcoma, myeloproliferative neoplasm (MPN), recurrent B-cell non-Hodgkin lymphoma, recurrent diffuse large B-cell lymphoma, recurrent Hodgkin lymphoma, relapsed/refractory multiple myeloma (RRMM), metastatic colorectal cancer (mCRC), metastatic castration-resistant prostate cancer (mCRPC), and lung cancer.

35. The use of any one of claims 32 to 34, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), and previously treated or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML).

36. The use of any one of claims 32 to 35, wherein the cancer is associated with refractory anemia, refractory anemia with ringed sideroblasts, or refractory anemia with excess blasts.

37. The use of any one of claims 32 to 36, wherein the medicament is to be administered with another therapeutic agent.

38. The use of claim 37, wherein the another therapeutic agent is one or more selected from the list consisting of: ADI-PEG 20, AMG-176, APG-115, APR-246, avelumab, bendamustine, bisantrene, brentuximab vedotin, capecitabine, CB-839, cisplatin, CS-01, cusatuzumab, cyclophosphamide, cytarabine, dasatinib, daunorubicin, DCLL9718S, decitabine, deferasirox, dexamethasone, durvalumab, eltrombopag, enasidenib, entinostat, entrectinib, enzalutamide, epacadostat, erythropoetin, etoposide,

evorpacept, filgrastim, fludarabine phosphate, flumatinib, gemcitabine, gemtuzumab ozogamicin, gilteritinib, GM-CSF, GSK2879552, HMPL-523, homoharringtonine, IBI188, ibrutinib, idarubicin, itacitinib, ivosidenib, jaktinib, KPT-8602, LDE255, lenalidomide, lirilumab, LP-108, magrolimab, MAX-40279, mitoxantrone, mitoxantrone liposome, mocetinostat, moxifloxacin, nivolumab, olutasidenib, omacetaxine, oxaliplatin, paclitaxel, pembrolizumab, pevonedistat, pinometostat, pracinostat, quizartinib, revlimid, rigosertib, rituximab, romidepsin, RP7214, S64315, S65487, sabatolimab, seclidemstat, selumetinib, siremadlin, sirolimus, SL-401, SNDX-5613, sorafenib, talazoparib, tamibarotene, tolinapant, trastuzumab, tucidinostat, tyrosine kinase inhibitor, uproleselan, velcade, venetoclax, vincristine, visilizumab, vorinostat, and vosaroxin.